Provider Playbook:
COVID-19 Outpatient Therapeutics

January 2022

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

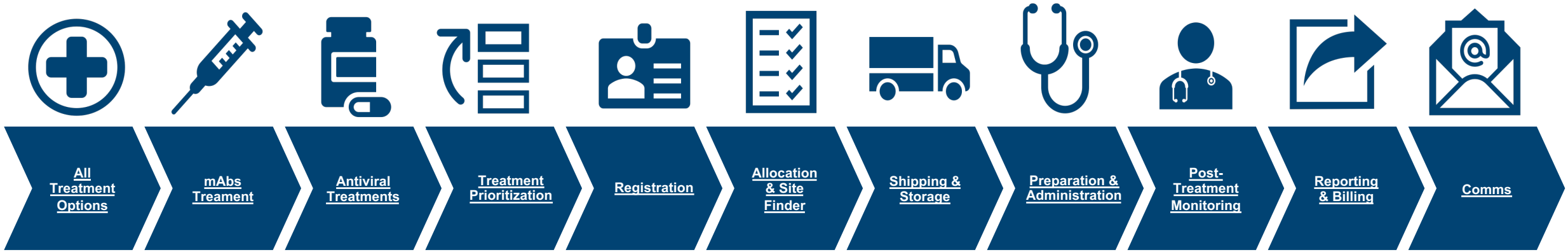
NC DHHS COVID-19 Response

PROVIDER PLAYBOOK: PREFACE

The policies outlined in this playbook should be regarded as guidance provided by the National Institute of Health (NIH), Food and Drug Administration (FDA), and the North Carolina Department of Health and Human Services (NC DHHS). This playbook does not cover every clinical scenario and providers should employ clinical decision making as allowed by their licensure scope of practice.

This playbook covers outpatient COVID-19 treatment options available in the state of North Carolina and associated provider guidance and responsibilities necessary to provide COVID-19 therapies.

CONTENT LAYOUT



All Treatment Options	mAbs Treament	Antiviral Treatments	Treatment Prioritization	Registration	Allocation & Site Finder	Shipping & Storage	Preparation & Administration	Post-Treatment Monitoring	Reporting & Billing	Comms
Slides 5 - 8	Slides 9 - 10	Slides 11 - 13	Slides 14 - 17	Slides 18 – 21	Slides 22 - 33	Slides 34 - 35	Slides 36 - 39	Slides 40 - 41	Slides 42 - 48	Slides 49 - 50

Additional Links and Resources

Therapeutics FAQs

Reference this site for FAQs regarding COVID-19 mAbs, oral antivirals, treatment, and other questions

NC Provider Office Hours

Attend weekly Zoom meetings on Fridays at 12pm for questions regarding therapeutic products and the ordering and allocation process (meeting invite link provided in Therapeutics Newsletter)

Therapeutics Inbox

Email the NC DHHS COVID-19 Therapeutics Inbox (Therapeutics.COVID19@dhhs.nc.gov) for urgent issues

TABLE OF CONTENTS

Please refer to this key throughout to find relevant information:
Monoclonal Antibodies Antivirals

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

All COVID-19 Treatment Options

PRODUCT SPECIFICATIONS (1 OF 3)

REGEN-COV

Please note: treatment is not authorized for use at this time due to the markedly reduced activity against the Omicron variant

- Manufactured by: Regeneron
- Authorized dosage for REGEN-COV for both treatment and as post-exposure prophylaxis is 600 mg of casirivimab and 600 mg of imdevimab administered together
- REGEN-COV is authorized for patients aged 12 and over
- For treatment, IV infusion is recommended
- Subcutaneous injection (shots administered underneath the skin) is an alternative route of administration when IV infusion is not feasible and would lead to delay in treatment
- For post-exposure prophylaxis, either intravenous infusion or subcutaneous injection is appropriate
- Providers should clinically monitor patients for at least one hour following the infusion/ injection for reactions
- Mixing and Dosing Instructions (linked)
- Visit the Health Care Provider Fact Sheet for further provider guidance and information

Bamlanivimab/Etesevimab

Please note: treatment is not authorized for use at this time due to the markedly reduced activity against the Omicron variant

- Manufactured by: Eli Lilly
- Authorized dosage for Bam/Ete for treatment is 700 mg of bamlanivimab and 1400 mg of etesevimab administered together
- Treatment can only be administered through an IV infusion of bamlanivimab and etesevimab as a single intravenous infusion via pump or gravity
- For post-exposure prophylaxis, use the same dosage as treatment and administer through IV infusion
- Authorized for post-exposure prophylaxis and treatment in all younger pediatric patients, including newborns
- The IV infusion will take 21-60+ minutes, dependent upon the providers' discretion
- Providers should clinically monitor patients for at least one hour after infusion is complete for reactions
- Mixing and Dosing Instructions (linked)
- Visit the Health Care Provider Fact Sheet for further provider guidance and information

PRODUCT SPECIFICATIONS (2 OF 3)

Sotrovimab

- Manufactured by: GlaxoSmithKline
- Authorized dosage for sotrovimab for treatment is 500 mg of sotrovimab
- Sotrovimab is authorized for patients aged 12 and over
- Treatment can only be administered through IV infusion
- The IV infusion should administer the entire bag of solution over 30 minutes
- Providers should clinically monitor patients for at least one hour after infusion is complete for reactions
- Mixing and Dosing Instructions (linked)
- Visit the Health Care Provider Fact Sheet for further provider guidance and information

EVUSHELD

- Manufactured: AstraZeneca
- Authorized dosage for EVUSHELD, formerly known as AZD7442, is a combination of two LAABs for pre-exposure prevention as 150 mg of tixagevimab and 150 mg of cilgavimab administered in two separate, consecutive injections
- EVUSHELD is approved for adults and adolescents with moderate to severe immune compromise who may not mount an adequate immune response to COVID-19 vaccinations
- EVUSHELD can only be delivered as an intramuscular dose
- EVUSHELD is not yet approved for COVID-19 prophylaxis and treatment
- While SARS-CoV-2 remains in circulation, individuals who qualify for EVUSHELD, per the conditions of the EUA, can be re-dosed every 6 months
- Providers should clinically monitor patients for at least one hour following the injection for reactions
- Visit the Health Care Provider Fact Sheet for further provider guidance and information

Paxlovid

- Manufactured by: Pfizer
- Authorized dosage for Paxlovid is a combination of 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet), with all three tablets taken together orally twice daily for 5 days, with or without food
- Dosage adjustment required for moderate renal impairment (eGFR ≥30 to <60 mL/min)
- Paxlovid is approved for adults and pediatric patients (age 12 and older)
- Paxlovid can only be delivered as an oral pill
- Paxlovid is approved for treatment in patients with a positive COVID-19 test who are at high risk for progression to severe COVID-19
- Providers should monitor patients with potential drug interactions for adverse reactions
- Visit the Health Care Provider Fact Sheet for further provider guidance and information

PRODUCT SPECIFICATIONS (3 OF 3)

Molnupiravir

- Manufactured by: Merck
- Authorized dosage for molnupiravir is 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food
- Molnupiravir is only approved for adults
- Molnupiravir can only be delivered as an oral pill
- Molnupiravir is approved for treatment in patients with a positive COVID-19 test who are at high risk for progression to severe COVID-19, and for whom alternative COVID-19 treatment options are not accessible or clinically appropriate
- Providers should monitor patients with potential drug interactions for adverse reactions
- Visit the Health Care Provider Fact Sheet for further provider guidance and information

Veklury (remdesivir)

- Manufactured: Gilead Sciences, Inc.
- Authorized dosage for Veklury varies, please refer to the dosage guidance here
- VEKLURY is a drug approved for the treatment of coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral testing, who are: Hospitalized, or Not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.
- Veklury can only be delivered as an intravenous (IV) infusion
- Providers should clinically monitor patients for at least one hour following the infusion for reactions
- Visit the Health Care Provider Fact Sheet for further provider guidance and information

mAbs Treatment

MONOCLONAL ANTIBODIES - OVERVIEW

Monoclonal antibodies, or mAbs, are antibodies made in a laboratory to fight a particular infection. The Food and Drug Administration (FDA) has issued **Emergency Use Authorization (EUA)** for the use of monoclonal antibody therapies for adult and pediatric patients aged 12 and older (Bam/Ete authorized for all ages). mAbs are given to patients with an infusion, subcutaneous injection, or intramuscular injection. They are used for treatment or prevention. There are four mAbs products currently authorized for use for COVID-19:

mAbs Generic Name	Also known as	Authorized Indication	Route of Administration	Dosing Regimen	Authorized Patient Population	Standing Order?*	Efficacy
Casirivimab / imdevimab	**REGEN-COV**	Post-exposure Prophylaxis, Treatment within 10 days of symptoms	Subcutaneous Injection; Intravenous Infusion	600 mg of both	Patients aged 12 years and older	No, rescinded January 24th	70% effective in preventing hospitalizations or deaths within five (5) days of symptom onset Reduced efficacy against Omicron
Bamlanivimab / etesevimab	**Bam/Ete**	Post-exposure Prophylaxis, Treatment within 10 days of symptoms	Intravenous Infusion	Dosage varies with weight	Patients of all ages, including neonates	No, rescinded January 24th	87% effective in preventing hospitalizations or deaths within five (5) days of symptom onset Reduced efficacy against Omicron**
Sotrovimab	**Sotrovimab**	COVID-19 Treatment within 10 days of symptoms	Intravenous Infusion	500 mg of sotrovimab	Patients aged 12 years and older	Yes, revised January 5th	79% effective in preventing hospitalizations or deaths within five (5) days of symptom onset Retained efficacy against Omicron**
Tixagevimab / cilgavimab	**EVUSHELD AZD7442**	Pre-exposure prophylaxis (PrEP)	Intramuscular Injection	Two simultaneous IM injections every six (6) months	Patients aged 12 years and older who are immunocompromised or have a contraindication for COVID-19 vaccines	No – per FDA/HHS	77% effective in preventing SARS-CoV-2 RT-PCR symptomatic illness. Retained efficacy against Omicron

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**Per the Public Readiness and Emergency Preparedness Act, pharmacies were added to the eligible providers and can now administer monoclonal antibody treatment*

***Bam/Ete and sotrovimab data is preliminary, have not published official studies yet regarding efficacy*

Antiviral Treatments

ORAL ANTIVIRALS - OVERVIEW

The FDA has issued **EUAs** for the use of oral antiviral therapies for adult and pediatric patients aged 12 and older (molnupiravir authorized for 18+ only). Oral antivirals are administered orally and only used for treatment. There are two (2) types of oral antivirals that have been authorized for use for COVID-19. Both therapeutics target mild-to-moderate COVID-19 for adults who are at risk of severe illness:

Generic Name	Also known as	Authorized Indication	Route of Administration	Administration Requirements	Dosing Regimen	Authorized Patient Population	Standing Order?	Efficacy
Molnupiravir	**MK-4482, Merck**	Treatment of mild-to-moderate COVID-19 in adults who are at risk for progressing to severe COVID-19 and for whom alternate treatment is not accessible or clinically appropriate	Oral	Must start within five (5) days of symptom onset Not recommended during pregnancy	800 mg twice-daily for five (5) days	Adult patients aged 18 years and older	No – per FDA/HHS	30% effective in preventing hospitalizations or deaths within five (5) days of symptom onset Omicron efficacy unknown, but works for other known variants
Paxlovid	**Nirmatrelvir / Ritonavir, Pfizer**	Treatment of mild-to-moderate COVID-19 in adult and pediatric patients (12+) who are at risk for progressing to severe COVID-19	Oral	Must start within five (5) days of symptom onset Dosage adjustment required for moderate renal impairment (eGFR ≥30 to <60 mL/min) Drug interactions list	300 mg of nirmatrelvir and 100 mg of ritonavir twice-daily for five (5) days	Patients aged 12 years and older	No – per FDA/HHS	88% effective in preventing hospitalizations or deaths within five (5) days of symptom onset Expected to maintain effectiveness across all variants

VEKLURY (REMDESIVIR)- OVERVIEW

Please Note: Veklury (remdesivir) is not allocated by the federal government and only available commercially.

The FDA has full approval for treatment in certain age groups and has issued an **EUA** to permit the emergency use of Veklury for treatment of suspected or laboratory confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg. Please note, Veklury (Remdesivir) is currently being investigated for treatment in non-hospitalized patients.

Please view full prescribing information here, https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf and NIH Guidance here.

Generic Name	Also known as	Authorized Indication	Route of Administration	Administration Requirements	Dosing Regimen	Authorized Patient Population	Standing Order?	Efficacy
Remdesivir	**Veklury®**	**Full FDA Approval** Treatment of COVID-19 for adult and pediatric patients who are hospitalized or not hospitalized and have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19	Intravenous Infusion	May only be administered in settings in which healthcare providers have immediate access to medications to treat severe infusion or hypersensitivity reactions and the ability to activate EMS For non-hospitalized patients, treatment must be initiated as soon as possible after diagnosis and **within seven (7) days of symptom onset**	**For patients weighing 40kg or greater:** 200mg loading dose on Day 1, followed by a once-daily maintenance dose of 100mg from Day 2 **For patients weighing less than 40kg:** 5mg/kg loading dose on Day 1, followed by a once-daily maintenance dose of 2.5mg/kg from Day 2 **Treatment duration**: Hospitalized patients - 5-10 days total, Non-hospitalized patients - 3 days total	**Full FDA Approval** Adults and pediatric patients (aged 12 years and older and weighing at least 40 kg)	No	87% effective at preventing hospitalization/death compared to placebo in non-hospitalized patients considered at high-risk for progression to severe COVID-19 Retains efficacy against Omicron
		EUA Treatment of COVID-19 for pediatric patients who are hospitalized or not hospitalized and have mild to moderate COVID-19 and are at high risk for progression to severe COVID-19				**EUA** Pediatric patients aged 12 years and older weighing 3.5kg to less than 40kg, or pediatric patients aged less than 12 years of age weighing at least 3.5kg		

Treatment Prioritization

PRIORITIZATION OF COVID-19 THERAPEUTICS

With the increase in cases of COVID-19 and the emergence of the Omicron variant of concern, there may be logistical or supply constraints that make it impossible to offer the available therapy to all eligible patients, making patient triage necessary. The NIH Panel prioritized the following risk groups for anti-SARS-CoV-2 mAb therapy based on four (4) key elements to include age, vaccination status, immune status, and clinical risk factors. The groups are listed by tier in descending order of priority. **At this time NCDHHS requests that all prescribers limit the use of all available COVID-19 therapies to patients that meet the Tier 1, Tier 2, or Tier 3 prioritization criteria of the NIH guidelines outlined below:**

Tier 1	• Immunocompromised individuals not expected to mount an adequate immune response to COVID-19 vaccination or SARS-CoV-2 infection due to their underlying conditions, regardless of vaccine status (see Immunocompromising Conditions below); *or* • Unvaccinated individuals at the highest risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with additional risk factors).
Tier 2	• Unvaccinated individuals at risk of severe disease not included in Tier 1 (anyone aged ≥65 years or anyone aged <65 years with clinical risk factors)
Tier 3	• Individuals who are up to date with COVID vaccines and at high risk of severe disease (anyone aged ≥75 years or anyone aged ≥65 years with clinical risk factors)

In addition to meeting one of the above criteria (for treatment or post-exposure pro-phylaxis), the patient self-attests to being moderately to severely immunocompromised and is at high-risk for progression to severe COVID-19, hospitalization, or death from COVID-19. Examples of immunocompromising condition include:

- Receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress the immune system
- Received a stem cell transplant within the last two (2) years or are taking medicine to suppress the immune system
- Moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

ALL TREATMENT PRODUCTS PRIORITIZATION

Treatment Products

For non-hospitalized patients with mild to moderate COVID-19 who are at high risk of disease progression, the NIH Panel recommends using one (1) of the following therapeutics (listed in order of preference):

1. Paxlovid (nirmatrelvir 300 mg with ritonavir 100mg)
2. Sotrovimab 500 mg
3. Remdesivir 200 mg* (currently considered off-label use)
4. Molnupiravir 800 mg

REGEN-COV and Bamlanivimab/Etesevimab

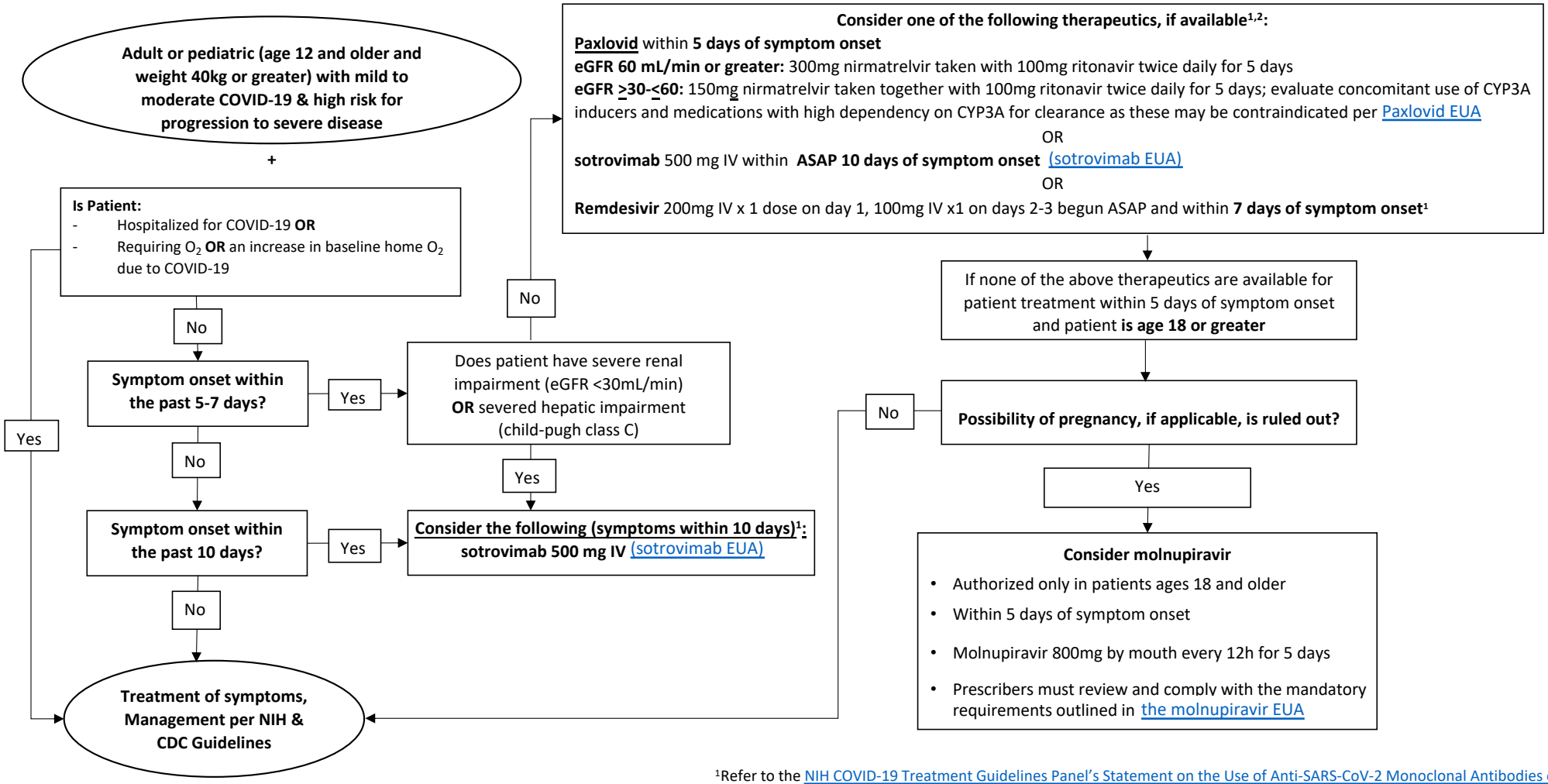
On January 24, 2022 the FDA revised the authorizations for two mAbs treatments—REGEN-COV (casirivimab and imdevimab); and bamlanivimab and etesevimab (administered together)—to limit the usage only when the patient is likely to have been infected with or exposed to a variant that is susceptible to these treatments.

As of January 15, 2022, the Centers for Disease Control and Prevention (CDC) estimated the Omicron variant of SARS-CoV-2 accounts for more than 99% of cases in the United States. It highly unlikely that COVID-19 patients currently seeking care are infected with a variant other than Omicron. As a result, REGEN-COV and Bamlanivimab/Etesevimab are **not authorized** for use, as these treatments are highly unlikely to be active against the Omicron variant.

**Remdesivir is not allocated by the federal government and is only available for private purchase*

MABS + ORAL ANTIVIRALS COVID-19 OUTPATIENT THERAPEUTICS DECISION GUIDE

The graphic below is a sample clinical decision guide provided by the Office of the Assistant Secretary for Preparedness and Response (ASPR)



Limited use of bamlanivimab/etesevimab and REGEN-COV as they are not expected to be active against the Omicron variant[1]

[1]Refer to the NIH COVID-19 Treatment Guidelines Panel's Statement on the Use of Anti-SARS-CoV-2 Monoclonal Antibodies or Remdesivir for the Treatment of Covid-19 in Nonhospitalized patients when Omicron is the Predominant Circulating Variant; Remdesivir is only approved for hospitalized individuals with COVID-19. Outpatient treatment is based on information from the literature (Dec 22, 2021 Early Remdesivir to Prevent Progression to Severe Covid-19 in Outpatients; DOI: 10.1056/NEJMoa2116846)

[2]COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease in either the outpatient or inpatient setting (COVID-19 Convalescent Plasma EUA)

Registration

NEW MABS PROVIDER REGISTRATION

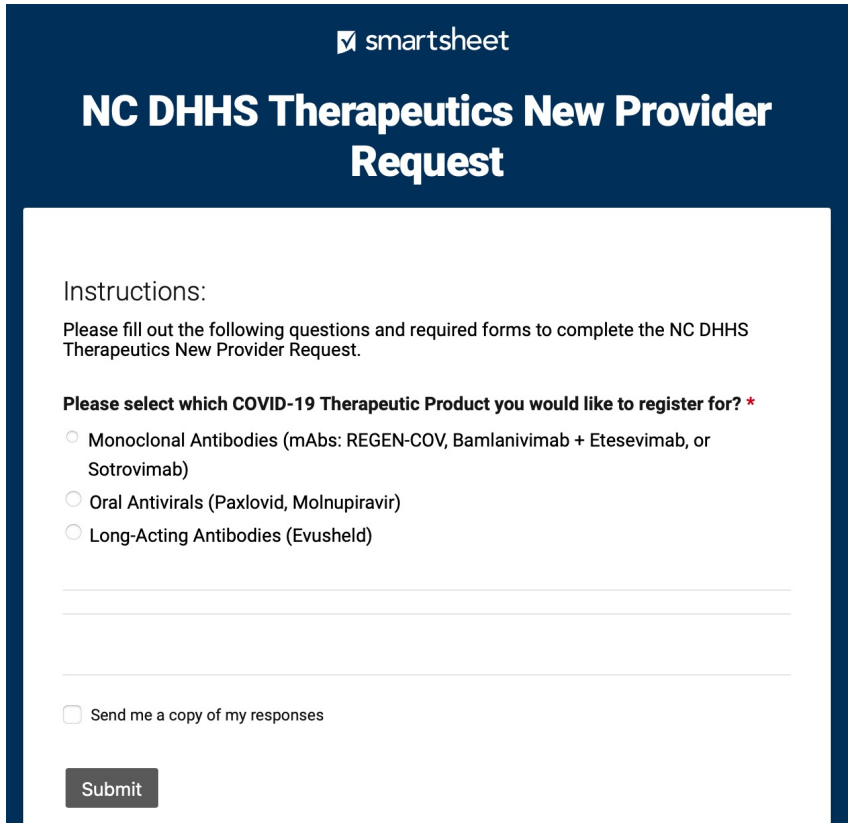
Providers can register with the state's COVID-19 treatment program for mAbs, oral antiviral pills, and all other COVID-19 therapeutic products by completing **NC DHHS Therapeutics New Provider Request Form**. Once completed, NC DHHS will submit the request to AmerisourceBergen (ABC) for processing.

Registration Requirements:

- **Locations with an active NC Board of Pharmacy License:**
  - Must include the license # and expiration date in the Therapeutics New Provider Request Form
  - Upload copy of active NC BOP license for location
- **Locations that DO NOT have an active NC Board of Pharmacy License:**
  - Complete Letter of Affiliation Form and upload in the Therapeutics New Provider Request Form
  - Upload copy of active NC medical license showing practitioners name & address

ABC reviews all requests to ensure requests are in line with the federal guidance on credentials.

If registration is approved, mAb provider locations will be eligible to request and receive mAbs allocations.



NEW EVUSHELD & ORAL ANTIVIRALS PROVIDER REGISTRATION

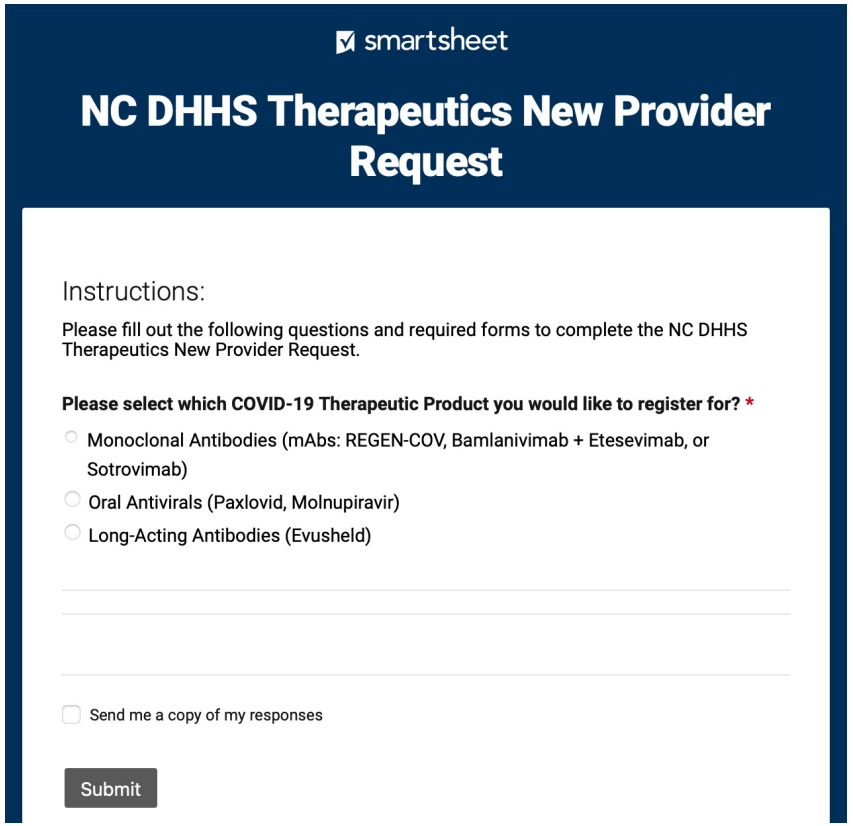
Providers can register with the state's COVID-19 treatment program for oral antiviral pills and all other COVID-19 therapeutic products by completing **NC DHHS Therapeutics New Provider Request Form**. Once completed, NC DHHS will create your account in HPOP as a registered provider.

Registration Requirements:

- When your account is created in HPOP you will receive an email shortly from vpop_no_reply@cdc.gov allowing you complete the enrollment process
- To activate your account, you must verify your sites address and receiving hours. You must complete these steps in order to request allocations

For additional guidance, you can visit the HPOP Provider Portal - Get Started

Please note that it will take 2-3 business days to process your registration. Registration does not guarantee that you will receive allocation.



ORAL ANTIVIRAL DISPENSING GUIDANCE

Physicians, advanced practice registered nurses, and physician's assistants with active licensure and in good standing with their respective governing bodies can prescribe and dispense oral antivirals for treatment of COVID-19 in accordance with the Paxlovid and molnupiravir EUAs, from their offices, if the following conditions are met:

1. There is absolutely no charge to the patient for the drug or act of dispensing, including seeking reimbursement of dispensing fees through third-party payors
2. Products are labeled in accordance with State and Federal dispensing laws. Details from the NC Board of Pharmacy on what information must be included on a prescription label can be found here

Physicians who wish to dispense oral antivirals for the treatment of COVID-19 (or any other medication) for a fee must be registered with the NC Board of Pharmacy as a dispensing physician.

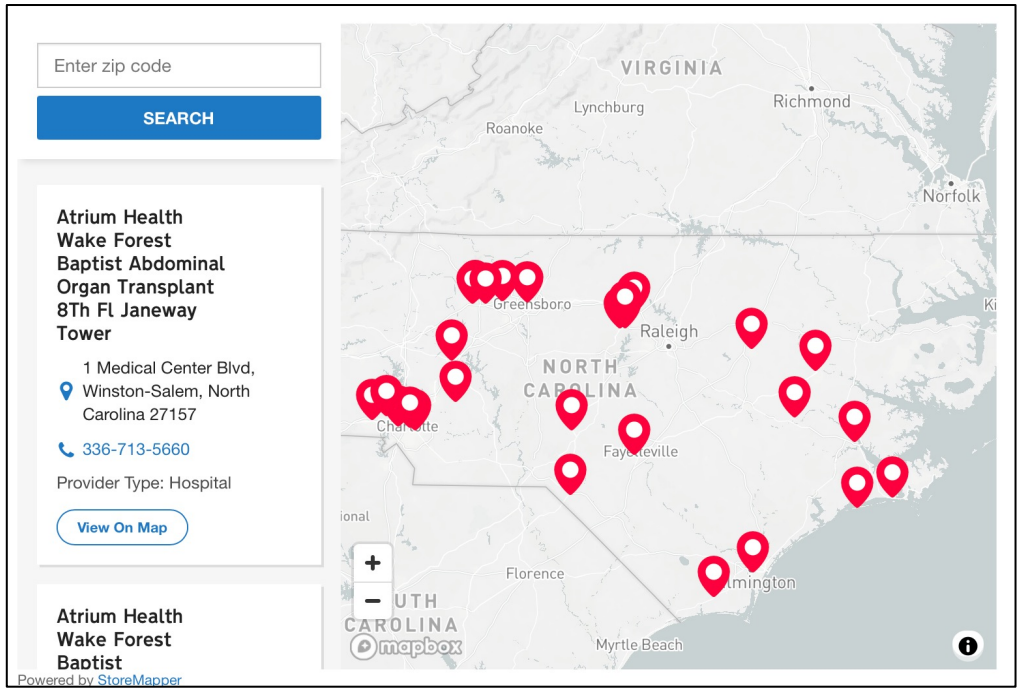
Nurse Practitioners and Physician's Assistants who wish to dispense medications other than COVID-19 therapeutics (whether a fee is charged or not) or who wish to dispense COVID-19 therapeutics for a fee must register with the Board of Pharmacy as a nurse practitioner or physician's assistant.

For more information on becoming a dispensing physician, nurse practitioner, or physician's assistant please visit the NC Board of Pharmacy Dispensing Physician, Physician Assistant and Nurse Practitioners Registration Requirements.

Allocation & Site Finder

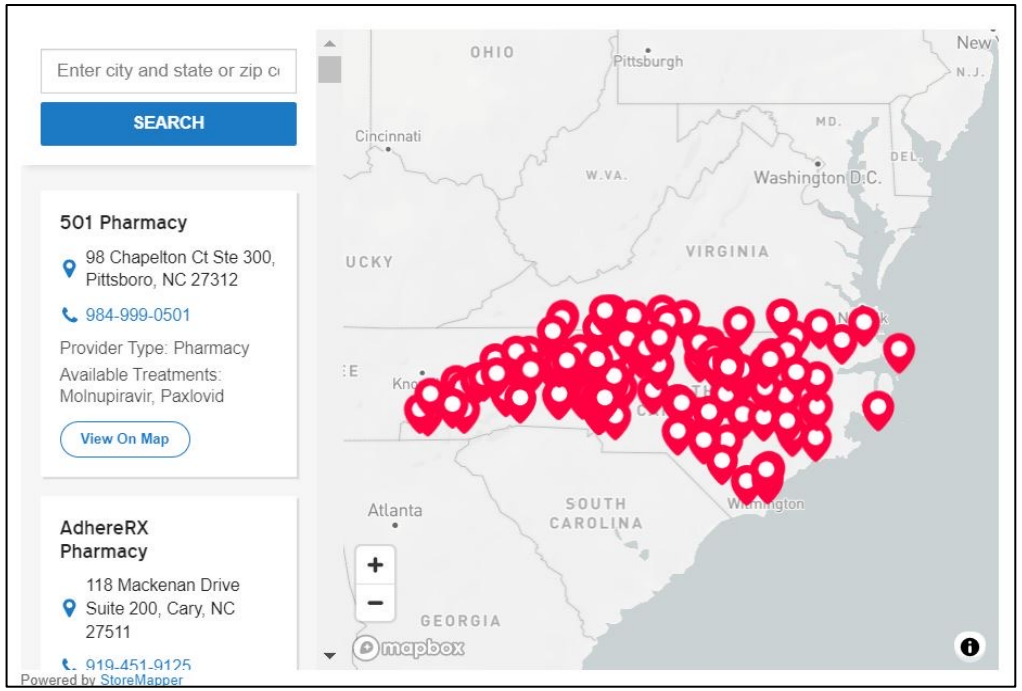
HOW TO LOCATE COVID-19 THERAPEUTICS

EVUSHELD Site Finder Tool



The 'Information For Individuals at Higher Risk' section on the NC DHHS website includes a 'Site Finder' tool specifically for EVUSHELD treatment locations

mAbs and Oral Antivirals Site Finder Tool



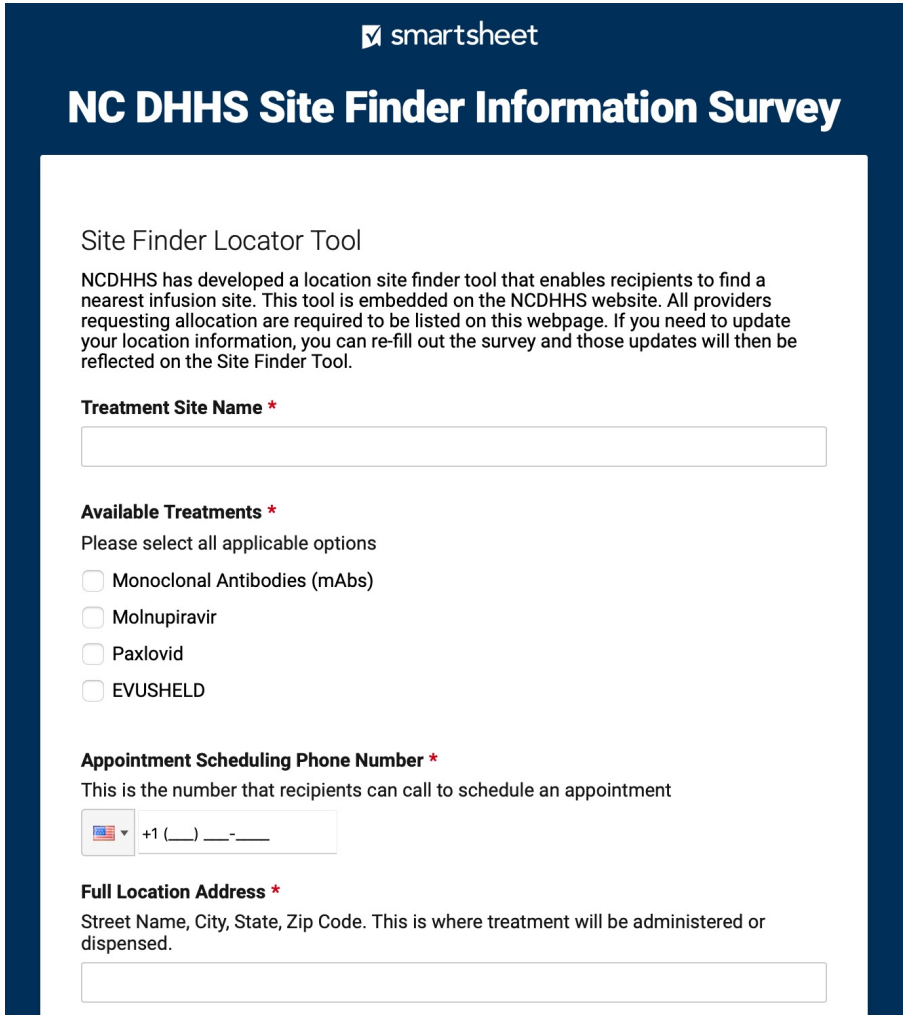
The 'Find COVID-19 Treatment' section on the NC DHHS website includes an updated 'Site Finder' tool that enables recipients to: 1) Search for nearby treatment sites, 2) Discover available treatments each site offers for administration, 3) Find resources to schedule an appointment (phone numbers, websites)

SITE FINDER REGISTRATION

All providers serving the greater population (excluding long-term care facilities) requesting mAbs or oral antivirals allocations are **required** to be listed on the NC DHHS website so that community members seeking treatment are aware your facility may be able to serve them. **All providers will be automatically added to the Site Finder upon receiving allocation or reporting administrations.**

To update, delete, or add missing information to your posting on the Site Finder tool, please complete the Site Finder Provider Information survey.

Your location will be listed on the mAbs and Oral Antivirals Site Finder Tool and/or the EVUSHELD Site Finder Tool embedded on the NC DHHS website. This ensures all eligible recipients can easily and equitably locate, access, and schedule appointments to receive this potentially lifesaving treatment.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NC DHHS Site Finder Information Survey

Site Finder Locator Tool

NCDHHS has developed a location site finder tool that enables recipients to find a nearest infusion site. This tool is embedded on the NCDHHS website. All providers requesting allocation are required to be listed on this webpage. If you need to update your location information, you can re-fill out the survey and those updates will then be reflected on the Site Finder Tool.

Treatment Site Name *

Available Treatments *

Please select all applicable options

- Monoclonal Antibodies (mAbs)
- Molnupiravir
- Paxlovid
- EVUSHELD

Appointment Scheduling Phone Number *

This is the number that recipients can call to schedule an appointment

+1 (___) ___-____

Full Location Address *

Street Name, City, State, Zip Code. This is where treatment will be administered or dispensed.

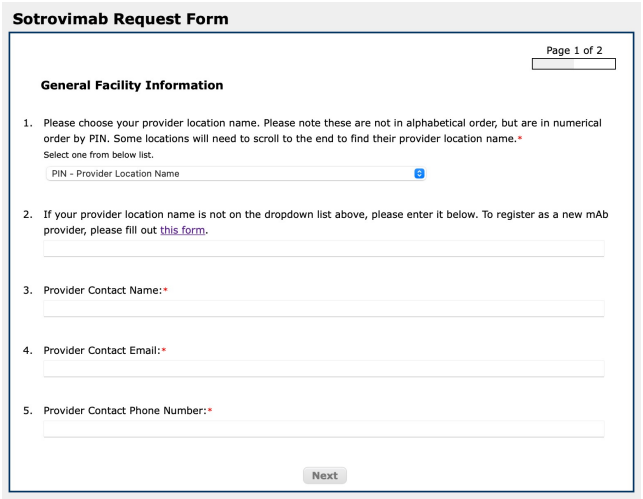
REQUESTING MABS ALLOCATIONS (1 OF 3)

NC DHHS is responsible for the **management and distribution of mAbs treatment allocations** requested by providers within the state.

To request product: Complete the Sotrovimab Allocation Request Survey.

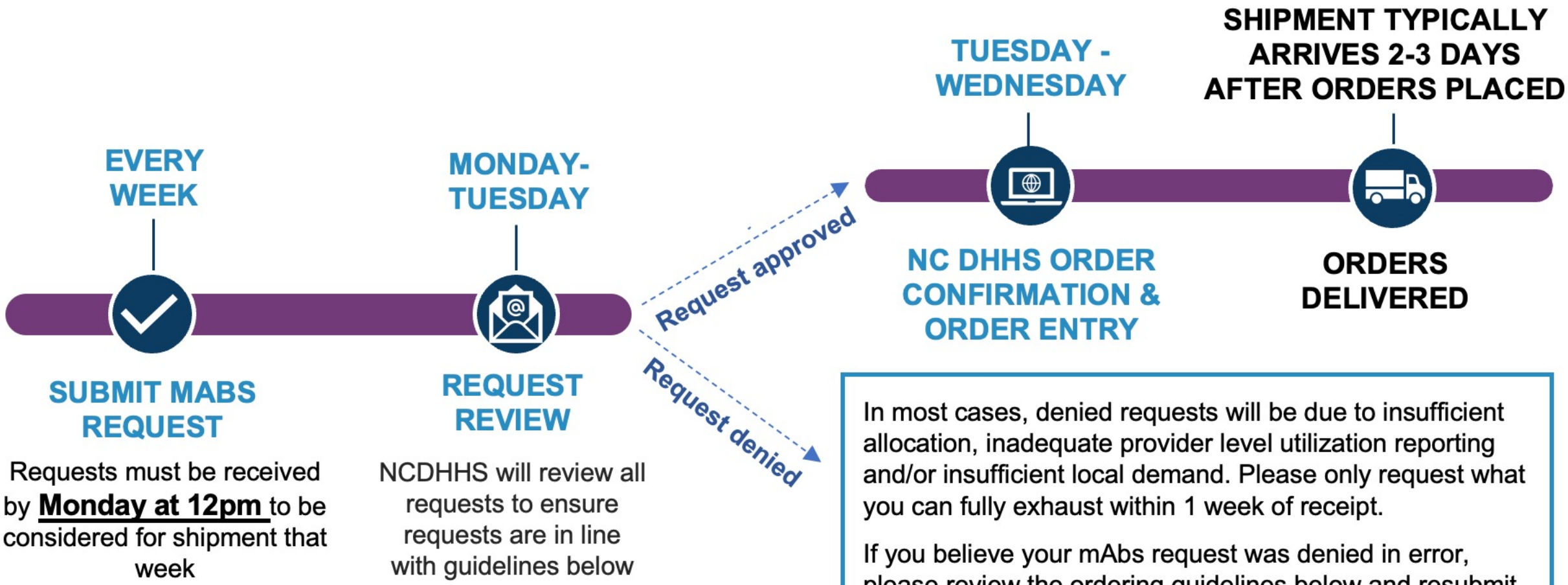
- Providers must be registered with AmerisourceBergen to request mAbs
- Providers must submit allocation requests by **Mondays every week at 12pm** to be eligible to receive mAbs shipments
- There is not an option to return product to the manufacturer. Please only request the number of courses you can **administer within seven (7) days**. If extra product is available on-hand, please facilitate a transfer with another facility in need of that product
- Providers should always submit allocation requests in number of courses

Confirmation of allocation request receipt is distributed from the Therapeutics Mailbox every Wednesday.



Sotrovimab Requests

REQUESTING MABS ALLOCATIONS (2 OF 3)



In most cases, denied requests will be due to insufficient allocation, inadequate provider level utilization reporting and/or insufficient local demand. Please only request what you can fully exhaust within 1 week of receipt.

If you believe your mAbs request was denied in error, please review the ordering guidelines below and resubmit to be considered in the next allocation.

To request and receive shipment, providers must be registered with AmerisourceBergen. For the current registration process, please refer to slide 18.

REQUESTING MABS ALLOCATIONS (3 OF 3)

NC DHHS reviews all requests to ensure orders align with state ordering guidelines and meet a specific set of criteria.

This criteria is determined by HHS on the number of weekly allocation amounts provided to the state and on the number of requests received by the state from the Allocation Request Forms submitted by providers. State ordering guidelines for mAbs is provided below:

	Sotrovimab
Minimum Order Quantity (MOQ)	**6**
Maximum Order Request	If requesting > MOQ: Only order enough inventory to meet **one (1) week of utilization demand**
Reporting Method	**All administrations must be reported via HHS tele-tracking & the State Inventory and Administration Survey** *Reporting mechanisms vary for hospitals*
Direct Ship Available	✓

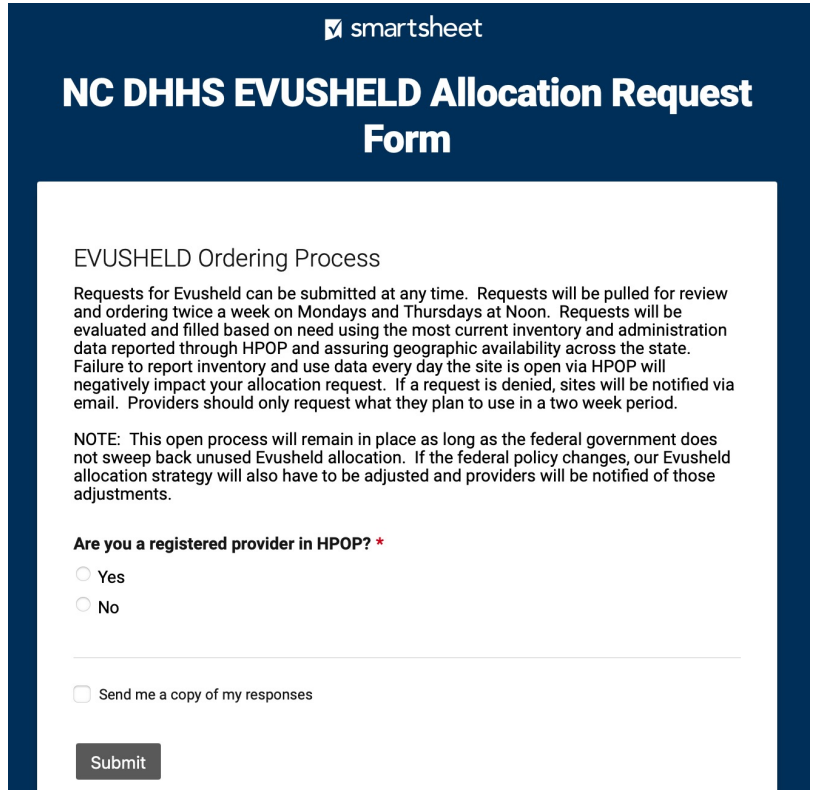
REQUESTING EVUSHELD ALLOCATION (1 OF 3)

NC DHHS is responsible for the **management and distribution of EVUSHELD allocations** requested by providers within the state.

To Request product: Complete the EVUSHELD Allocation Request Form.

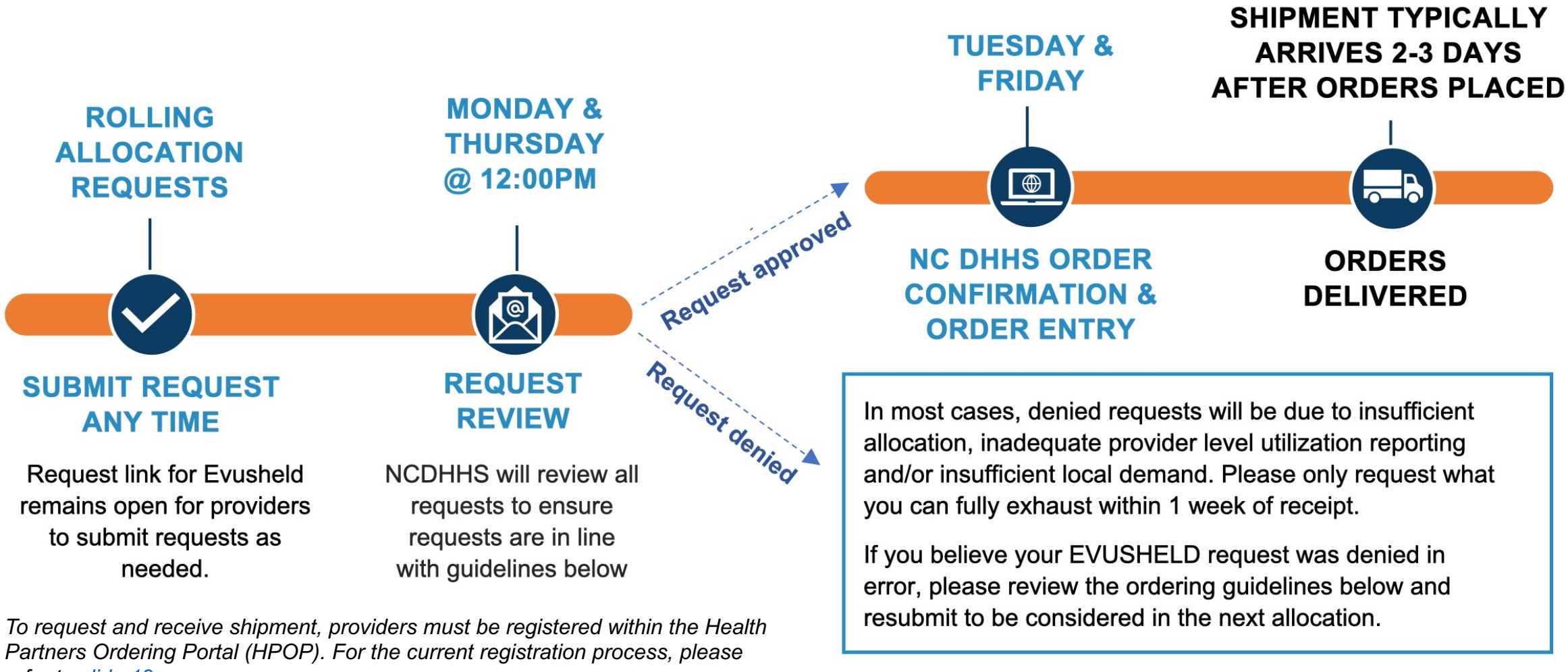
- **Providers can submit allocation requests at any time**. Requests will be processed twice a week on Mondays and Thursdays at 12pm ET
- There is not an option to return product to the manufacturer. Please only request the number of courses you can **administer within seven (7) days**. If extra product is available on-hand, please facilitate a transfer with another facility in need of that product
- Providers should always submit allocation requests in number of courses

Confirmation of allocation request receipt is distributed from the Therapeutics Mailbox every Tuesday & Friday.



EVUSHELD Requests

REQUESTING EVUSHELD ALLOCATIONS (2 OF 3)



To request and receive shipment, providers must be registered within the Health Partners Ordering Portal (HPOP). For the current registration process, please refer to slide 19.

REQUESTING EVUSHELD ALLOCATIONS (3 OF 3)

NC DHHS reviews all requests to ensure orders align with state ordering guidelines and meet a specific set of criteria.

This criteria is determined by the HHS on the number of weekly allocation amounts provided to the state and on the number of requests received by the state from the Allocation Request Forms submitted by providers. State ordering guidelines for EVUSHELD is provided below:

	AstraZeneca's EVUSHELD
Minimum Order Quantity (MOQ)	**24**
Maximum Order Request	If requesting > MOQ: Only order enough inventory to meet **one (1) week of utilization demand**
Reporting Method	**All administrations must be reported via the HPOP**
Direct Ship Available	✓

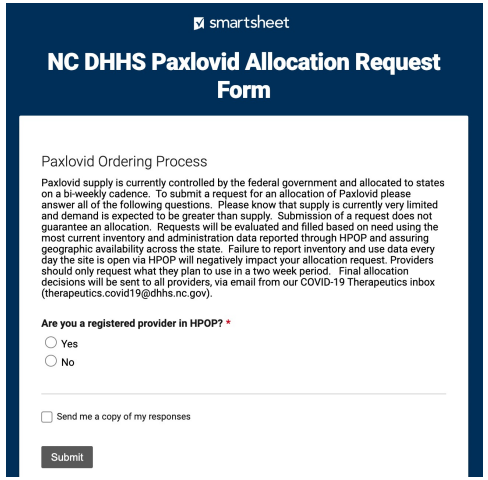
REQUESTING ORAL ANTIVIRALS ALLOCATION (1 OF 3)

NC DHHS is responsible for the **management and distribution of oral antivirals treatment allocations** requested by providers within the state.

To request product: Complete the Paxlovid Allocation Request Survey and/or the Molnupiravir Allocation Request Survey.

- Providers must be registered in HPOP to request oral antivirals
- Providers must submit oral antiviral allocation requests by **Mondays every other week at 12pm** to be eligible to receive shipment
- There is not an option to return product to the manufacturer. Please only request the number of courses you can **administer within two (2) weeks**. If extra product is available on-hand, please facilitate a transfer with another facility in need of that product
- Providers should always submit allocation requests in number of courses

Confirmation of allocation request receipt is distributed from the Therapeutics Mailbox every other Wednesday.


smartsheet

NC DHHS Paxlovid Allocation Request Form

Paxlovid Ordering Process

Paxlovid supply is currently controlled by the federal government and allocated to states on a bi-weekly cadence. To submit a request for an allocation of Paxlovid please answer all of the following questions. Please know that supply is currently very limited and demand is expected to be greater than supply. Submission of a request does not guarantee an allocation. Requests will be evaluated and filled based on need using the most current inventory and administration data reported through HPOP and assuring geographic availability across the state. Failure to report inventory and use data every day the site is open via HPOP will negatively impact your allocation request. Providers should only request what they plan to use in a two week period. Final allocation decisions will be sent to all providers, via email from our COVID-19 Therapeutics inbox (therapeutics.covid19@dhhs.nc.gov).

Are you a registered provider in HPOP? *

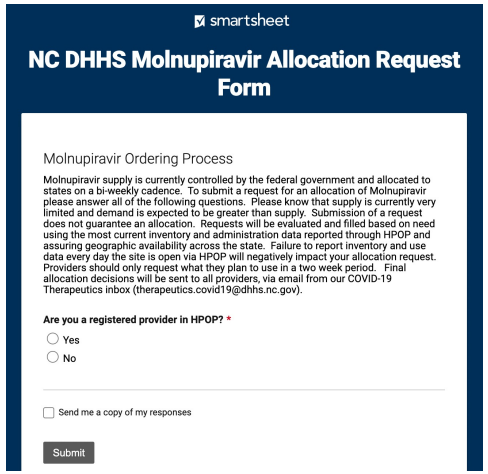
Yes

No

Send me a copy of my responses

Submit

Paxlovid Requests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NC DHHS Molnupiravir Allocation Request Form

Molnupiravir Ordering Process

Molnupiravir supply is currently controlled by the federal government and allocated to states on a bi-weekly cadence. To submit a request for an allocation of Molnupiravir please answer all of the following questions. Please know that supply is currently very limited and demand is expected to be greater than supply. Submission of a request does not guarantee an allocation. Requests will be evaluated and filled based on need using the most current inventory and administration data reported through HPOP and assuring geographic availability across the state. Failure to report inventory and use data every day the site is open via HPOP will negatively impact your allocation request. Providers should only request what they plan to use in a two week period. Final allocation decisions will be sent to all providers, via email from our COVID-19 Therapeutics inbox (therapeutics.covid19@dhhs.nc.gov).

Are you a registered provider in HPOP? *

Yes

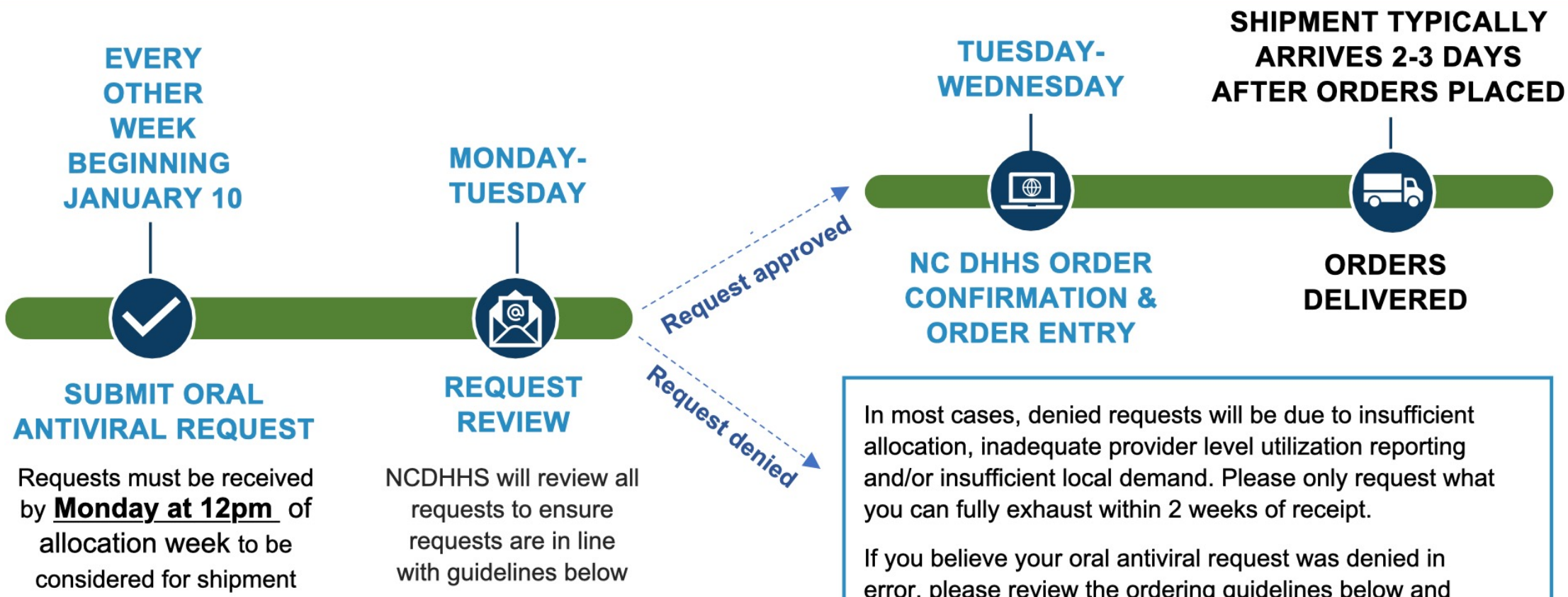
No

Send me a copy of my responses

Submit

Molnupiravir Requests

REQUESTING ORAL ANTIVIRALS ALLOCATIONS (2 OF 3)



In most cases, denied requests will be due to insufficient allocation, inadequate provider level utilization reporting and/or insufficient local demand. Please only request what you can fully exhaust within 2 weeks of receipt.

If you believe your oral antiviral request was denied in error, please review the ordering guidelines below and resubmit to be considered in the next allocation.

To request and receive shipment, providers must be registered within the HPOP. For the current registration process, please refer to slide 19.

REQUESTING ORAL ANTIVIRALS ALLOCATIONS (3 OF 3)

NC DHHS reviews all requests to ensure orders align with state ordering guidelines and meet a specific set of criteria.

This criteria is determined by the HHS on the number of weekly allocation amounts provided to the state and on the number of requests received by the state from the Allocation Request Forms submitted by providers. State ordering guidelines for oral antivirals is provided below:

	Merck's Molnupiravir	Pfizer's Paxlovid
Minimum Order Quantity (MOQ)	**20**	**20**
Maximum Order Request	If requesting > MOQ: Only order enough inventory to meet **two (2) weeks of utilization demand**	
Reporting Method	**All administrations must be reported daily via the HPOP when location is open**	
Direct Ship Available	✓	✓

Shipping & Storage

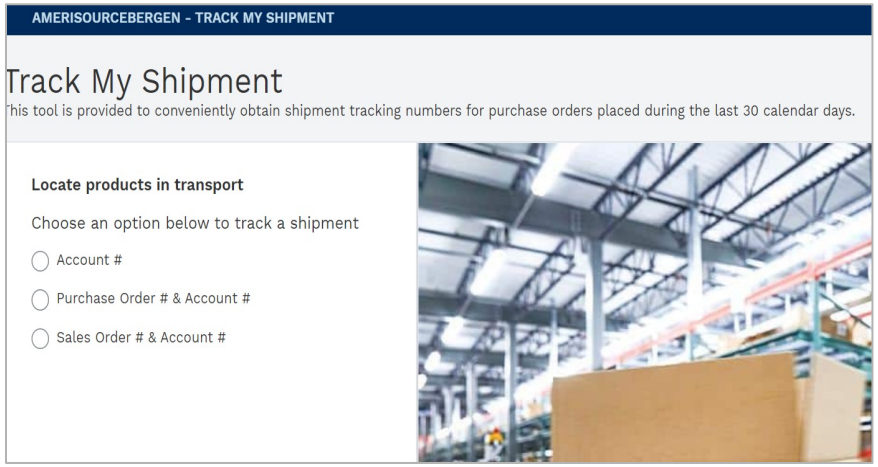
SHIPPING & STORAGE

Shipping:

ABC **fulfills and ships mAb and oral antiviral product orders**. NC DHHS does not control these functions.

Visit ABC's Tracking Tool Website to track order status.

- Use account # provided by ABC
- ABC delivers the drug to the site of care
- The product is shipped refrigerated and must be stored refrigerated
- If request is approved, NC DHHS confirms and enters orders by Friday of the same week. Expected delivery time of orders is the following Tuesday at the latest
- For access and more information regarding ABC shipping, contact customersystemsupport@AmerisourceBergen.com



Storage:

- **mAbs:** Provider must store product refrigerated at 2° C to 8° C (36° F to 46° F) in the original carton to protect from light before use. Discard any unused portion. DO NOT FREEZE. DO NOT SHAKE
- **Oral Antivirals:** Store at USP controlled room temperature 20° C to 25° C (68° F to 77° F); excursions permitted between 15° C to 30° C (59° F to 86° F)

Preparation & Administration

MABS PREPARATION & ADMINISTRATION

Upon receipt of mAbs product(s), providers must adhere to the following federal requirements:

1) Administration preparation process:

- Prepare sterile infusions in a manner consistent with local laws, regulations, guidelines and policies
- Obtain new vial(s) and/or IV bags if the drug product contains any visible particulate matter

2) Needs for space to prepare mAb drug:

- Dedicated preparation area, in addition to sufficient administration capacity onsite or nearby

3) Acceptable equipment for mAb drug storage:

- Refrigerated storage (2-8° C)
- Temperature control mechanism, including temperature monitoring process

mAbs can be prepared for infusion and subcutaneous administration bedside by any qualified medical professional.

Please see EUA manufacturer fact sheet for drug-specific requirements.

ORAL ANTIVIRALS PREPARATION & ADMINISTRATION

Upon receipt of oral antiviral product(s), providers must adhere to the following requirements:

1) Dosage & administration:

- **Molnupiravir:** The dosage in adult patients is 800 mg (four 200 mg capsules) taken orally every 12 hours for five (5) days, with or without food
  - Take molnupiravir as soon as possible after a diagnosis of COVID-19 has been made, and within five (5) days of symptom onset
  - Completion of the full five-day treatment course and continued isolation in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2
  - Molnupiravir is not authorized for use for longer than five (5) consecutive days because the safety and efficacy have not been established
- **Paxlovid:** The dosage for PAXLOVID is 300 mg nirmatrelvir (two 150 mg tablets) with 100 mg ritonavir (one 100 mg tablet) with all three tablets taken together orally twice daily for five (5) days, with or without food
  - Prescriptions should specify the numeric dose of each active ingredient within PAXLOVID
  - Completion of the full five-day treatment course and continued isolation in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2
  - Dosage adjustment required for moderate renal impairment (eGFR ≥30 to <60 mL/min). Pharmacists should discard the removed tablets per state requirements or local guidelines. Please refer to the HCP Letter for further information

2) Acceptable equipment for oral antiviral drug storage:

- USP Controlled Room Temperature 20° C to 25° C (68° F to 77° F)
- Excursions permitted between 15° C to 30° C (59° F to 86° F)

Please see EUA manufacturer fact sheet for drug-specific requirements

REGEN-COV PACKAGING & LABELING INFORMATION

Please be aware that REGEN-COV has multiple packaging types, and it is essential you take note of the differences when administering the product.

Packaging: The REGEN-COV™ may arrive in one of two (2) packaging configurations:

1) REGEN-COV™ Dose Packs (2-Vial) or
2) Casirivimab and Imdevimab Co-Pack (two (2) vials per carton): **One Carton allows for preparation of two (2) treatment doses**

It is important that providers and those mixing and/ or administering the product pay close attention to the dosage and refer to the QR code enclosed with the product for updates. Please refer to the Labeling and Packaging one pager and Regeneron website for the latest information and instructions for each formulation.

Labeling:

- In addition to the packaging configurations noted above, some REGEN-COV™ carton and vial labels may have statements such as “Solution for Intravenous Administration” or “For Intravenous Infusion after Dilution.”
- Any of these REGEN-COV™ vials may be used to prepare and administer intravenous infusions as well as subcutaneous injections, even though there is no language on the label that that states the subcutaneous route is appropriate.

Post-Treatment Monitoring

POST-TREATMENT PATIENT MONITORING

mAbs

1. Provide to and review with the patient: COVID-19 Antibody Therapy Discharge Instructions
2. Patients treated with monoclonal antibody therapy should continue to use infection precautions and isolate or quarantine according to CDC Criteria for Quarantine and Isolation
3. Administrators of monoclonal antibody therapy should report all medication errors and serious adverse events within seven (7) days from the onset of the event. This can be found here: http://www.fda.gov/medwatch/report.htm. Please note, all fields should be completed with as much detailed information as possible

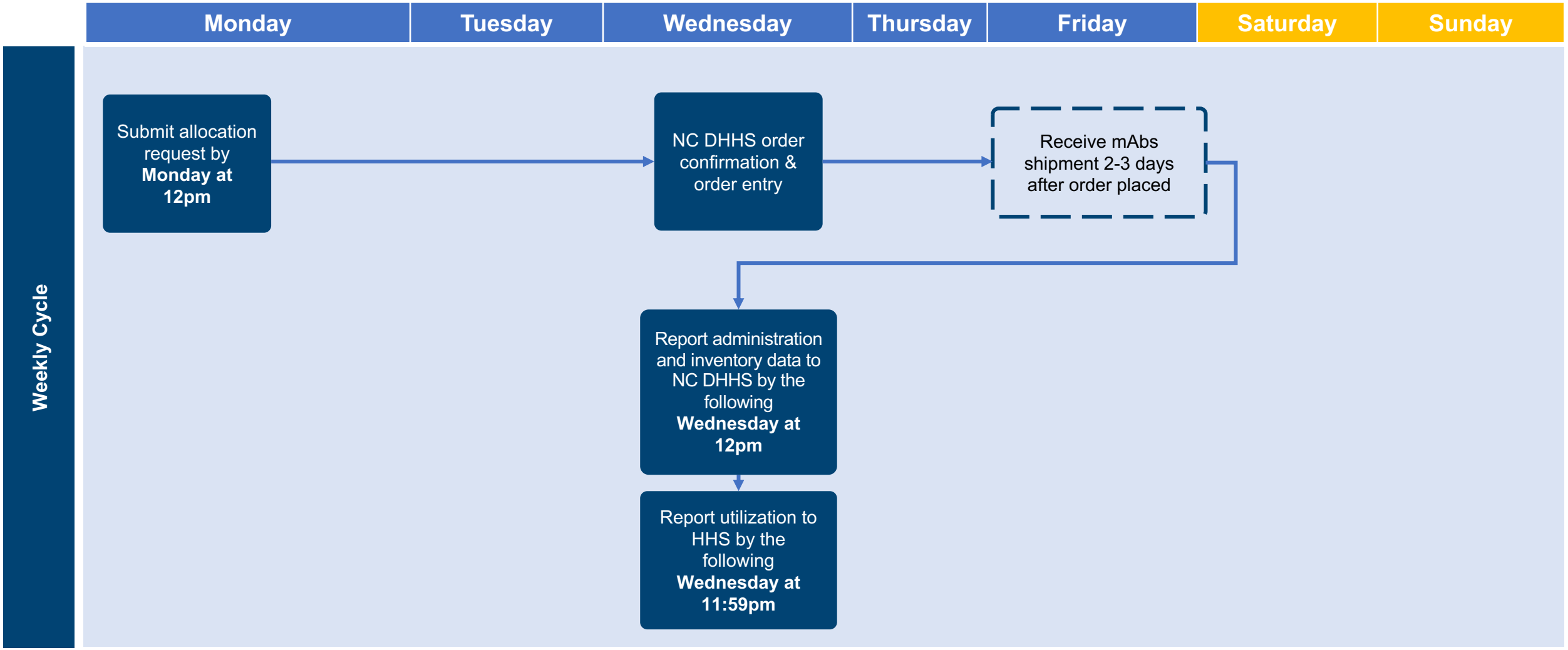
Oral Antivirals

1. No drug interactions have been identified based on the limited available data on the emergency use of molnupiravir authorized under this EUA
2. Refer to the EUA Fact Sheet for Paxlovid to identify potential drug interactions to prevent elevated plasma concentrations
3. Treatment of overdosage for Molnupiravir and Paxlovid should consist of general supportive measures, including monitoring of vital signs and observations of the clinical status of the patient

Reporting & Billing

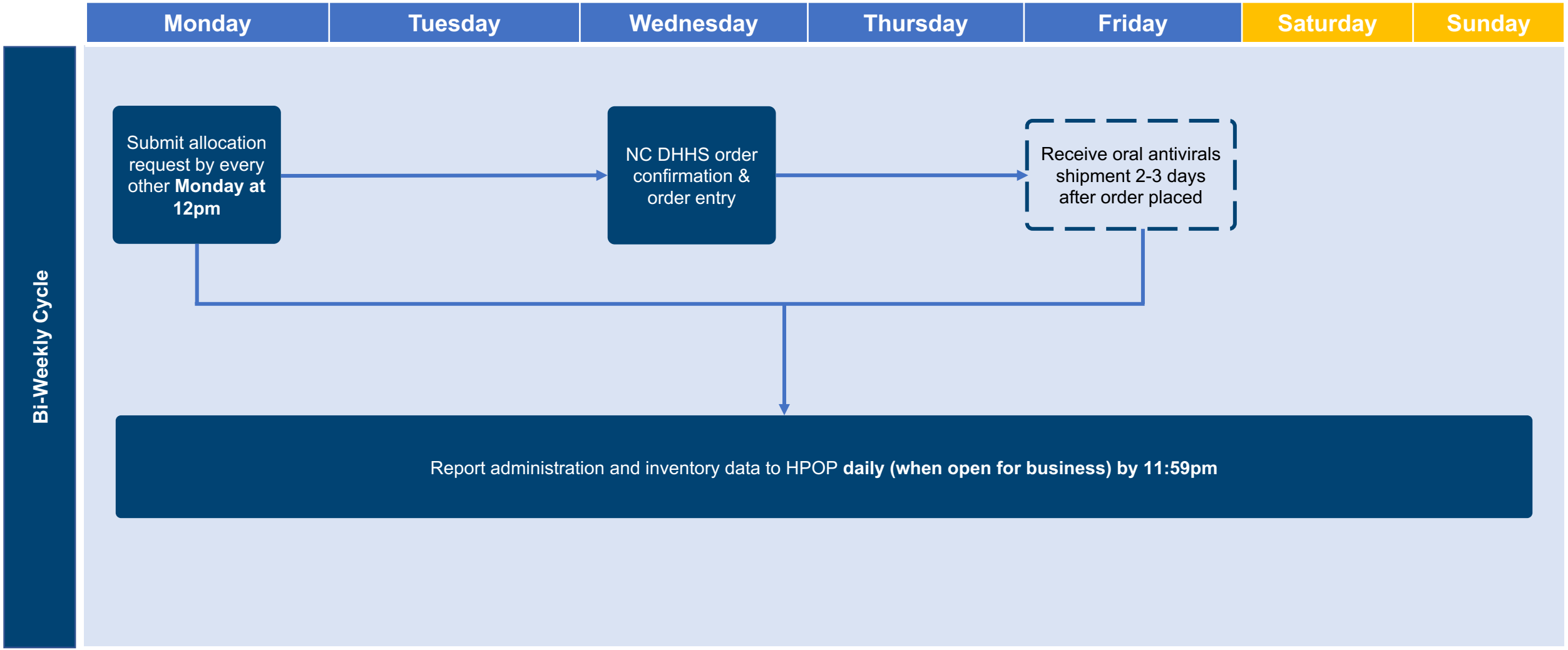
PROVIDER MABS ALLOCATION REPORTING CADENCE

The graphic below illustrates provider cadence for mAbs allocation requests and reporting to NC DHHS and HHS.



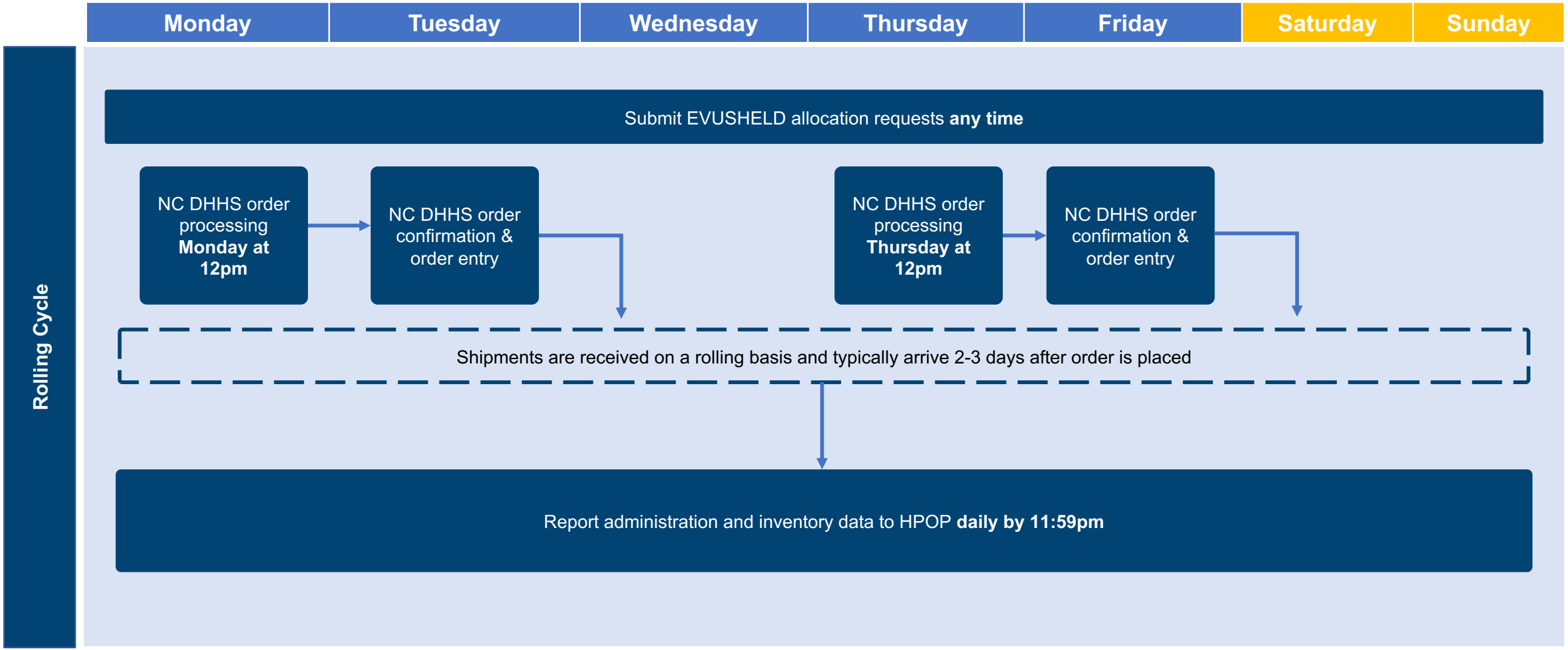
PROVIDER ORAL ANTIVIRALS ALLOCATION REPORTING CADENCE

The graphic below illustrates provider cadence for oral antivirals allocation requests and reporting to NC DHHS and HHS.



PROVIDER EVUSHELD ALLOCATION REPORTING CADENCE

The graphic below illustrates new provider cadence for EVUSHELD allocation requests and reporting to NC DHHS and HHS.



REPORTING REQUIREMENTS

Weekly Cadence HHS Reporting:

Although the NC DHHS oversees distribution and management of mAbs treatments to provider locations within the state, **ALL administrating locations must continue to report via HHS tele-tracking** (reporting mechanisms may vary for hospitals). Information updates will continue to be uploaded on the HHS tele-tracking site.

Weekly reminders and instructions will also continue to be emailed to existing providers from TeleTracking's Technical Support at hhs-protect@teletracking.com.

First-time users will receive enrollment and reporting instructions in an e-mail from protect-noreply@hhs.gov with the subject line of "Invitation: HHS TeleTracking COVID-19 Portal." This email provides step-by-step instructions to access the Portal for the first time.

Utilization reporting due **Wednesdays at 11:59am**

Daily HPOP Reporting:

Although the NC DHHS oversees distribution and management of EVUSHELD and Oral Antivirals (Molnupiravir and Paxlovid) to provider locations within the state, **ALL administrating locations must report administration and inventory data in HPOP DAILY for all days the location is open**. Reporting is not required when the facility is closed and not available for administering or dispensing.

Weekly Cadence Administration and Inventory Reporting:

Although the NC DHHS oversees distribution and management of mAbs treatments to provider locations within the state, **ALL administrating locations must continue to report administration and inventory data** via this form (reporting mechanisms may vary for hospitals).

Weekly reminders and instructions will also continue to be emailed to existing providers from the Therapeutics Inbox.

Admin and Inventory reporting due **Wednesdays at 12pm**.

ADVERSE EVENT REPORTING

The prescribing healthcare provider and/or the provider's designee are/is responsible for mandatory reporting of all serious adverse events and medication errors potentially related to the respective drug product within seven (7) days from the healthcare provider's awareness of the event, using FDA Form 3500 (for information on how to access this form, see below).

Submit adverse event and medication error reports, using Form 3500, to FDA MedWatch using one of the following methods:

- Complete and submit the report online by visiting www.fda.gov/medwatch/report.htm
- Complete and submit a postage-paid FDA Form 3500 and return by:
  - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20851-9787, or
  - Fax to 1-800-FDA-0178
- Call 1-800-FDA-1088 to request a reporting form

Please provide a copy of all FDA MedWatch forms to:

Product	Company	E-mail/Website	Fax Number	Phone Number
REGEN-COV	Regeneron Pharmaceuticals	medical.information@regeneron.com	1-888-876-2736	1-844-734-6643
Bam/Ete	Eli Lilly and Company	mailindata_gsmtindy@lilly.com	1-317-277-0853	1-855-545-5921
Sotrovimab	GlaxoSmithKline	WW.GSKAEReportingUS@gsk.com	1-919-287-2902	1-866-475-2684
EVUSHELD	AstraZeneca	https://contactazmedical.astrazeneca.com	1-866-742-7984	1-800-236-9933
Paxlovid	Pfizer	www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985
Molnupiravir	Merck Sharp & Dohme Corp.	dpoc.usa@msd.com	1-215-616-5677	

BILLING & REIMBURSEMENT

Please reference the following link for more detailed billing information:

- COVID-19 Monoclonal Antibody: Coding and Billing Guide
- Centers for Medicare & Medicaid Services (CMS) Guidance on Oral Antiviral Billing
- National Community Pharmacists Association COVID-19 Antivirals Dispensing and Reimbursement

CMS Code for Outpatient Veklury (remdesivir) Use

- Following the recent statement from National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel regarding therapies for COVID-19 Omicron variant, CMS created **HCPCS code J0248** for the Veklury (remdesivir) antiviral medication when administered in outpatient setting
- Code available for use by all payers
- Effective dates of service on or after December 23, 2021:
  - Long descriptor: Injection, remdesivir, 1 mg
  - Short descriptor: Inj, remdesivir, 1 mg
- Medicare Administrative Contractors (MACs) determine Medicare coverage when no national coverage determination, including when providers use FDA-approved drugs for indications other than what is on approved label
- MACs will determine Medicare coverage for HCPCS code J0248 for Veklury (remdesivir) administered in outpatient setting
- See CMS COVID-19 Provider Toolkit for additional information

Comms

THERAPEUTICS COMMUNICATION

Providers can subscribe to the **NC DHHS Therapeutics Communication** to learn more about weekly updates and news. Weekly updates are sent out on Wednesdays. Confirmation of allocation request receipt is sent out on Fridays.

To get added to the distribution list, complete the NC DHHS Therapeutics Provider Communications form:

- If you would like to **add more than one email** to the distribution list, refresh page after submission and resubmit
- **Please note**, that there will be a separate link shared for new providers to register for a mAbs or oral antivirals account. Completing this form will only get you added to the NC DHHS therapeutics communications distribution list

Please send all questions to: Therapeutics.COVID19@dhhs.nc.gov